REMARKS

Reconsideration and allowance of the captioned patent application are respectfully requested. The captioned patent application addresses compounds of formula I and uses thereof for the treatment or prevention of diabetes, obesity and related conditions.

The Examiner rejected the application under 35 USC 112 alleging that the claims are non-enabled for treating some of the diseases and conditions recited in the claims, and for prevention as to all of the conditions recited. The Examiner indicated that the specification is enabling for the treatment of some disorders, such as obesity, diabetes mellitus, obesity-related disorders, such as diabetes and breast cancer. This indication is appreciatively acknowledged. Additionally, the Examiner alleged that the claims were non-enabled for compounds in which Z represents CR^1. Applicants have addressed the Examiner's concerns, and respectfully traverse as set forth below.

Applicants have amended the claims in response to the Official Action. Claims 1, 12, 13, 20 and 31 have been amended, and claims 8, 9, 19 and 28 have been cancelled. Claim 20 addresses treatment or prevention of obesity or diabetes. Claim 31 addresses the treatment of diabetes or obesity, and claim 32 addresses treating or preventing obesity-related disorders.

With respect to the conditions other than diabetes and obesity, Applicants urge that this amendment renders the objection as to these other conditions moot. Applicants maintained the treatment and prevention language for diabetes, obesity and the obesity-related disorders that are recited in the claims because within the context of the present application, treatment and prevention as to these diseases and conditions are fully enabled. Prevention of diabetes, obesity and obesity related disorders has been fully developed in the art, so that one of ordinary skill is able to recognize a patient that is prone to developing these conditions, using no more than routine medical tests, without resort to undue experimentation. Physicians perform such tests and analyses on patients on a regular basis, so to allege that this constitutes experimentation that is "undue" fails to take into account the routine nature of the tests that are utilized, and the high level of ordinary skill in the medical community.

In support of the Examiner's position with respect to non-enablement, it was alleged that one of ordinary skill would need to synthesize the compound, formulate it into a suitable dosage form, and then subject it to clinical trials. Applicants respectfully disagree that this would constitute undue experimentation or that this renders the application non-enabling. Taking into account the teachings of the specification, the application provides more than sufficient detail to teach one of ordinary skill how

to make the compounds of formula I. Starting on page 47, and ending on page 71, Applicants have provided 18 general schemes, designated Scheme A through Scheme R, which set forth the details necessary for one of ordinary skill to make the claimed compounds. Applicants then set out schemes 1 through 5, including the synthesis of any necessary intermediates, and 134 examples of compounds made taking into account the schemes that are provided.

With respect to dosing and administration, Applicants have provided an example of a dosage form (capsules) on page 89, as well as general dosing and administration at page 35, line 33 through page 37, line 10. Specifically, dosing for obesity is provided at page 36, lines 3 through 9; dosing for obesity related disorders is provided at page 36, lines 18 through 23, and dosing for diabetes is provided at page 36, lines 10 through 17. Dose selection within the ranges and specific examples provided in the application are well within the level of ordinary skill in the art for the medical practitioner.

In particular, with respect to the allegations concerning dosage, a dosing range has been provided, along with specific doses at page 36. For example, in treating diabetes, a range of about 0.07 mg to about 350 mg is provided at page 36, line 15. Similar ranges are provided for treating obesity, sexual dysfunction and the like. Oral compositions are described wherein doses from about 0.1 mg to about 1500 mg are recited at page 36, lines 27-32. The Examiner's allegation that a 100,000 fold dose range is "recommended" is not correct. Applicants have not made dosing recommendations. Moreover, a wide (or broad) dosing range is not to be treated as non-enabling simply because it is broad, particularly in view of examples and narrower sub-ranges for dosing that have been provided, and the high level of skill embodied in the treating physician, as the Examiner has pointed out. Precise dosing amounts have been disclosed as noted above, and these serve as useful starting points for the physician. It is well within the level of ordinary medical skill to adjust doses to reach the desired effect without undue experimentation.

Hence, Applicants have more than met their enablement burden with regard to the making and use of the compounds of formula I, since virtually no experimentation would be required of those of ordinary skill, above and beyond the content of the specification. It would thus appear that the Examiner is objecting to the amount of work that would be required to commercialize a drug product. While Applicants agree that drug development is detailed and time consuming, this is not a consideration in determining whether the amount of experimentation required to make and use an invention described in a patent application is "undue" so as to render it in violation of 35 USC 112.

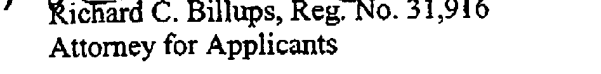
With respect to the selection of a particular disease or condition to be treated, a correlation exists in the art, which is well recognized by those skilled in the art, between melanocortin-4 agonists and the treatment of diseases and conditions that are mediated by melanocortin-4, and thus treatable by administering a compound that agonizes the melanocortin-4 receptor. Nothing presented in the application has been alleged by the Examiner to be inherently unbelievable or incredible, and the mere fact that numerous diseases and conditions are recited does not make them non-enabled. All are properly enabled because all of the diseases and conditions recited have been addressed in the art as mediated by melanocortin-4. Hence, it is not improper to claim a method of treating them as in the present application.

With respect to the Examiner's comment pertaining to the phrase "disorders, disease or conditions . . . . .", this language has been deleted from the claims, rendering the Examiner's allegation moot.

With respect to the Examiner's position regarding compounds in which Z represents CR^1, the definition of A has been amended. Applicants disagree that compounds wherein Z represents CR^1 are non-enabled, and reserve the right to continue prosecution thereof by filing a divisional or continuation application as appropriate.

It is respectfully urged that the claims are in allowable condition. Such action is respectfully requested. If the Examiner has any questions in connection with the captioned application she is respectfully requested to telephone the undersigned.

Respectfully submitted,

By 

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